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09/864,389	05/25/2001	Jacob Richter	2390/49704	1194

7590

09/26/2003

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EXAMINER

BUI, VY Q

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 09/26/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/864,389

Applicant(s)

PINCHASIK ET AL

Examiner

Vy Q. Bui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 31-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 and 42-49 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 18,19,21.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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## DETAILED ACTION

### *Drawings*

The corrected drawings (Figs. 7-8) were received on 7/7/2003. These corrected drawings are accepted.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

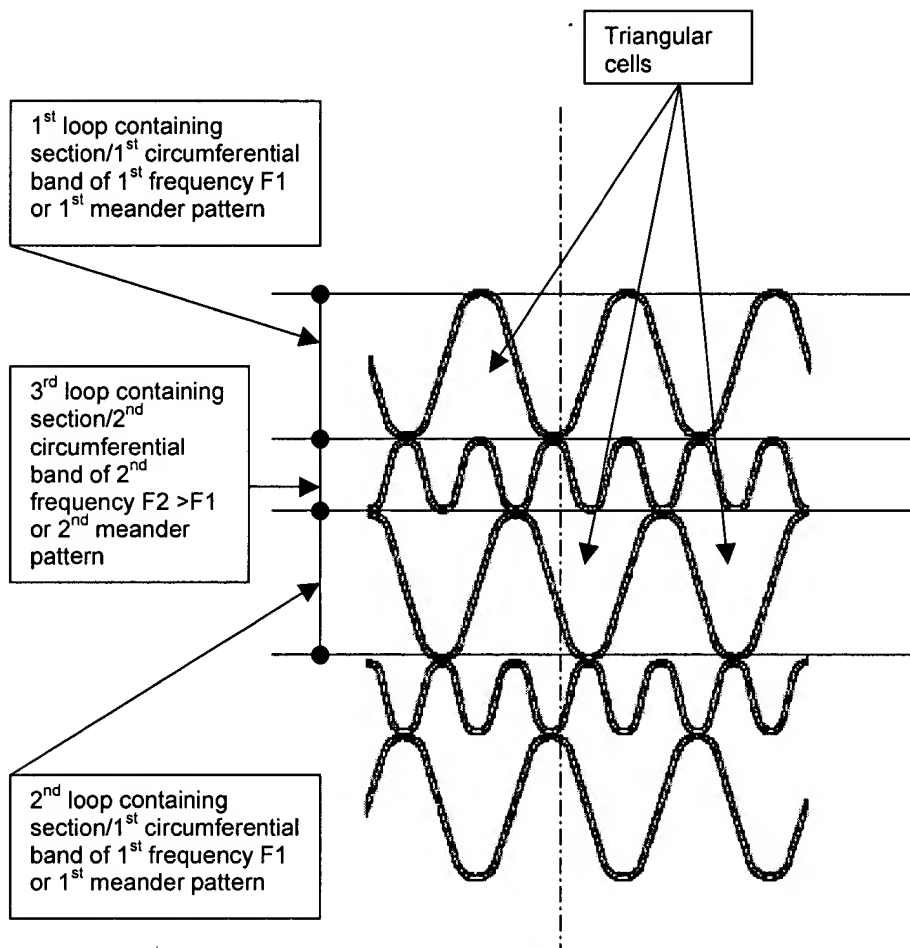
(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

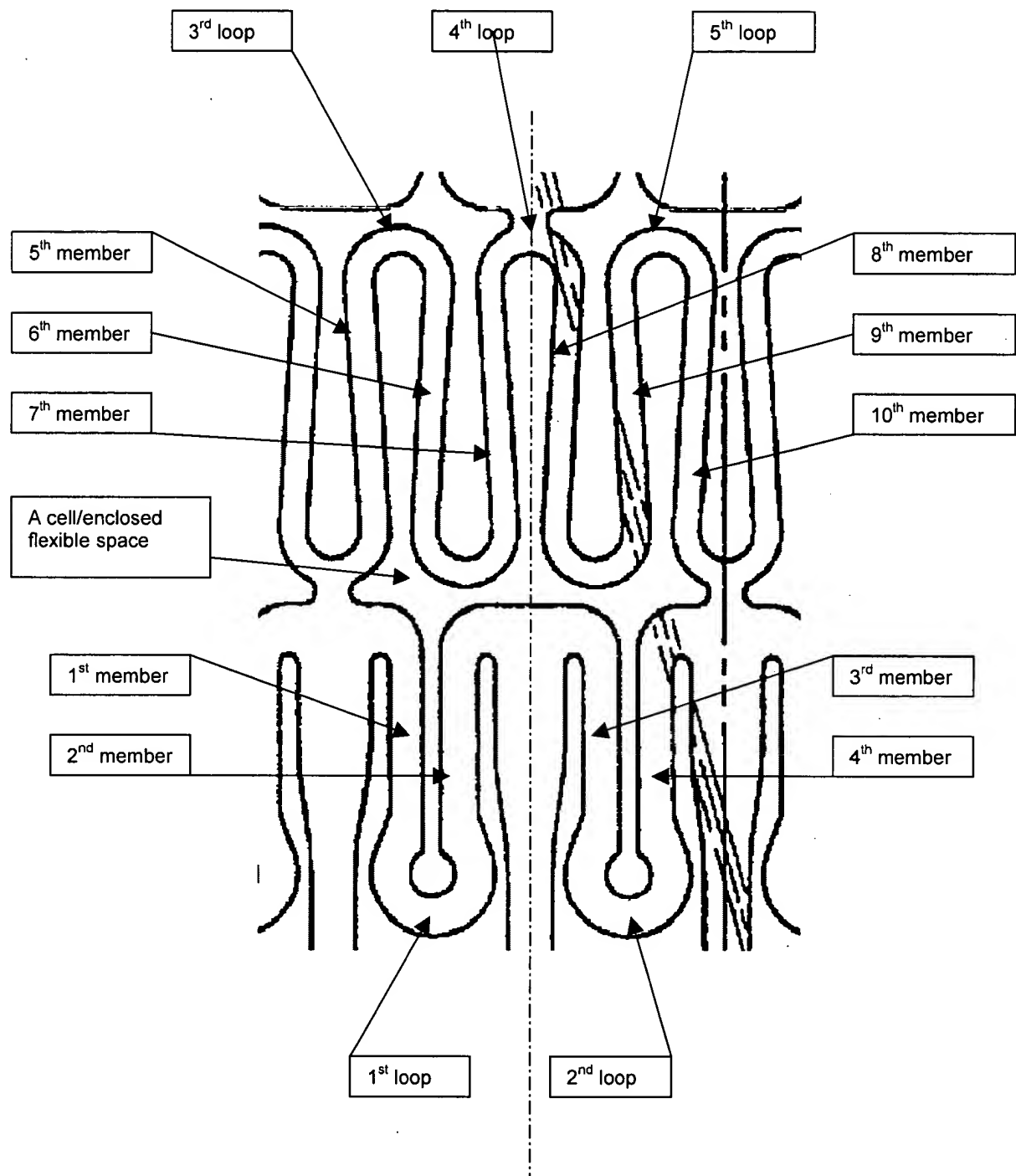
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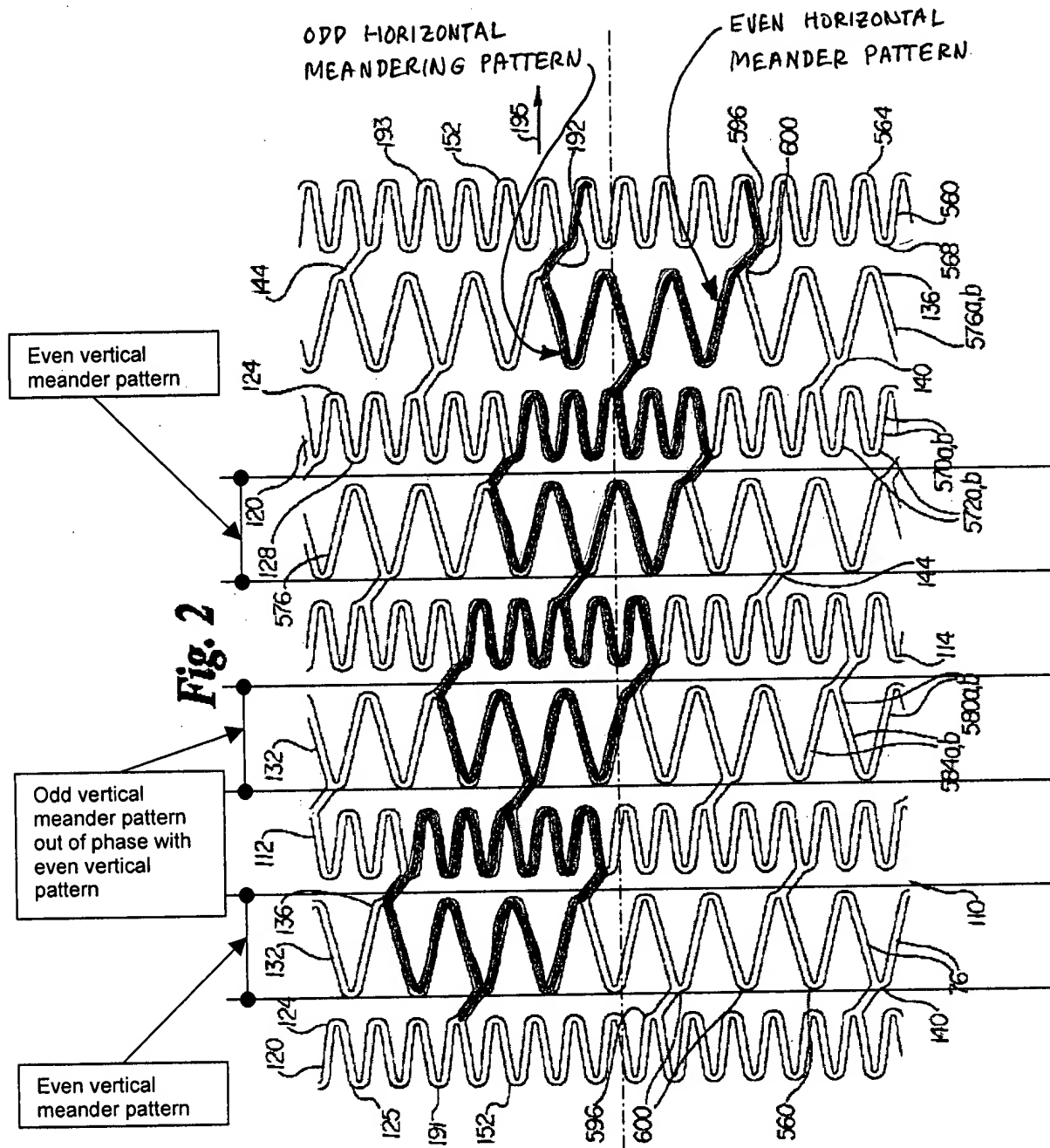
*Fig. 30*

(JAYARARAMAN)

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A cell in Fig. 5, BERRY et al.



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1. Claims 1-2, 4, 6-7, 11-12, 14, 16-17, 19, 42-47 are rejected under 35 U.S.C. 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over JAYARAMAN (6,162,245).

As to claims 1-2, 4, 6-7, 11-12, 14, 16-17, 19, 42-47, JAYARAMAN (see Fig. 30 on page 3 above) shows a stent structure comprising 1<sup>st</sup> and 2<sup>nd</sup> loop containing sections/1<sup>st</sup> circumferential bands/1<sup>st</sup> meander pattern of a 1<sup>st</sup> frequency F1, 3<sup>rd</sup> loop containing sections/2<sup>nd</sup> circumferential bands/2<sup>nd</sup> meander pattern of 2<sup>nd</sup> frequency F2 > F1 to define cells/triangular cells as recited in the claims.

Notice that JAYARAMAN stent comprises:

a. 3<sup>rd</sup> loop containing sections are configured in a sinusoidal shape of a frequency F2 higher than a frequency F1 of 1<sup>st</sup> and 2<sup>nd</sup> loop containing sections (Fig. 30, page 3 above), therefore 3<sup>rd</sup> loop containing sections do expand or contract when the stent structure is bent/expanded, thus 3<sup>rd</sup> loop containing sections do contribute to the cells elongating or shortening when the stent is in a curved configuration/expanded configuration. In addition, because the 3<sup>rd</sup> loop containing sections have more stored length (or more springy/wavy than 1<sup>st</sup> and 2<sup>nd</sup> loop containing sections), the 3<sup>rd</sup> loop containing sections are more flexible and more sensitive to deformation than 1<sup>st</sup> and 2<sup>nd</sup> loop containing sections, therefore during flexing of the stent, 3<sup>rd</sup> loop containing sections contribute more to the stent deformation than 1<sup>st</sup> and 2<sup>nd</sup> loop containing sections.

Alternatively, it would have been obvious to one of ordinary skill in the art to size/configure the 3<sup>rd</sup> loop containing sections so as to make the 3<sup>rd</sup> loop containing sections more flexible than the 1<sup>st</sup> and 2<sup>nd</sup> loop containing sections as this modification of size and shape to make a stent having sections more flexible (for increasing overall flexibility of the stent) than other more rigid sections (for radial strength to keep the lumen of the vessel to open) is well known in the art.

b. Cells/triangular cells in one side of a neutral axis of bending of the JAYARAMAN stent will be in a tension condition and in the other side of the neutral axis will be in a compression condition. Cells under the tension condition

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will open in length and narrow circumferentially and cells under the compression condition will shorten in length but widen circumferentially.

2. Claims 21-22, 24, 48-49 are rejected under 35 U.S.C. 102(a) as being anticipated by BROWN et al. (WO 00/30563 or US 20020007212 A1).

As to claims 21-22, 24, 48-49, BROWN (Fig. 2, page 5, this paper) shows even 1<sup>st</sup> meander patterns substantially are 180 degree out of phase with odd 1<sup>st</sup> meander patterns. Even 1<sup>st</sup> and odd 1<sup>st</sup> meander patterns alternate with and are spaced from each other to form a uniform flexible structure as recited in the claims. When expanded in a curved vessel, BROWN shows cells that increase in length in one side of a neutral axis/bending axis and cells that decrease in length in another side of the neutral axis.

3. Claims 26-27, 29 are rejected under 35 U.S.C. 102(e) as being anticipated by BERRY et al. (6,231,598).

As to claim 26, BERRY (see BERRY Fig. 5 and BERRY triangular cell in page 4, this paper). Notice that BERRY stent comprises many flexible triangular cells to form a uniform mesh of flexible cells. Each BERRY triangular cell has a central axis BB. When expanded in a curved vessel, BERRY triangular cell will increase in length in one side of the neutral axis and decrease in length in one side of the neutral axis as recited in the claim.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.



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1. Claims 3, 5, 13, 15, 18, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over JAYARAMAN (6,162,245) as applied to claims 1-2, 4, 6-7, 11-12, 14, 16-17, 19 above, and further in view of YANG et al (6,120,847).

JAYARAMAN discloses substantially all limitations recited in the claims, except for the stent is coated with a medicine for treatment purpose. However, coating a stent with a medicine or drug is well known in the art. For example, YANG discloses a method for coating a therapeutic substance on the surface of the stent for local treatment of a blood vessel. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a medicine coating to JAYARAMAN stent so as to have the medicine distributed directly to the treatment site of a blood vessel.

2. Claims 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over are rejected under 35 U.S.C. 102(a) as being anticipated by BROWN et al. (WO 00/30563 or US 20020007212 A1) as applied to claims 21-22, 24 above, and further in view of YANG et al (6,120,847).

BROWN discloses substantially all limitations recited in the claims, except for the stent is coated with a medicine for treatment purpose. However, coating a stent with a medicine or drug is well known in the art. For example, YANG discloses a method for coating a therapeutic substance on the surface of the stent for local treatment of a blood vessel. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a medicine coating to BROWN stent so as to have the medicine distributed directly to the treatment site of a blood vessel.

3. Claims 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over BERRY et al. (6,231,598) as applied to claims 26-27, 29 above, and further in view of YANG et al (6,120,847).

BERRY discloses substantially all limitations recited in the claims, except for the stent is coated with a medicine for treatment purpose. However, coating a

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stent with a medicine or drug is well known in the art. For example, YANG discloses a method for coating a therapeutic substance on the surface of the stent for local treatment of a blood vessel. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a medicine coating to BERRY stent so as to have the medicine distributed directly to the treatment site of a blood vessel.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 2 (line 2), 4 (line 2), 7 (line 2), 9 (line 2), 11 (line 14), 16 (line 9), 21 (line 12), 26 (line 34) recite the limitation "the curve". There are insufficient antecedent basis for this limitation in the claims.

### ***Claim Objections***

Claim 9 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim 4. Claim 9 is identical to claim 4. Claim 10 dependent to claim 9 is also objected.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

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***Response to Amendment***

The amendment and "Remarks" filed on 7/7/2003 under 37 CFR 1.131 has been considered but is moot in view of new grounds of rejection.

***Conclusion***

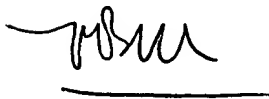
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 703-306-3420. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



VQB

9/17/2003.